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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SRIVASTAVA, KAILASH C	
ART UNIT	**PAPER NUMBER**
1657	

MAIL DATE	DELIVERY MODE
06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/827,341	NAKAO, KAZUWA	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 10-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response and amendment filed 15 March 2007 in response to Office Action mailed 15 September 2006 is acknowledged and entered.

2. The Art Unit Location to which your application has been assigned at the United States Patent and Trademark Office (i.e., USPTO) is Art Unit 1657.To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1657.

CLAIMS STATUS

3. Claims 1-17 are pending.

Restriction/Election

4. Election of Group II, Claims 6-9 with traverse filed 15 March 2007 in response to Office Action mailed 15 September 2006 is acknowledged and entered. Applicants' traversal is on the grounds that the restriction requirement cited *supra* is improper because:

- Citing MPEP §808.02, applicants argue that USPTO has not established separate classification and separate status for each of the inventive Groups;

- Applicants also argue, "the USPTO must show that examination of the claims would involve substantially different prior art searches"; and

- Citing MPEP §803.01, applicants argue "even though claims are directed to independent and distinct inventions" examining Claims 1-17 in one single application would not be burdensome because all the groups have the same component, viz., a guanylyl cyclase B (i.e., GC-B) activator.

Regarding "restriction requirement cited *supra* being improper, Applicants are absolutely correct in arguing that the invention in Claims 1-17 encompassed in inventive Groups I-IV according to Office Action mailed 15 September 2006 have a common component, i.e., guanylyl

cyclase B (i.e., GC-B) activator. Consequently, claims should not be separated into 4 different inventive groups. Applicants, however, at the same time admit on record that inventive Groups I-IV according to Election/Restriction requirement mailed 15 September 2006, "are directed to independent and distinctive inventions" (See Remarks filed 15 March 2007, Page 2, Lines 24-25). Applicants cannot have it both ways. Since the claimed subject matter in Claims 1-17 is "directed to independent and distinct inventions" as the applicants note in the above cited recitation, the restriction requirement in the Office Action mailed 15 September 2006 is proper. Consequently, there will be a search burden to examine Claims 1-17 together in one single application. Accordingly, said restriction requirement is not "improper".

Regarding applicants' arguments that the "USPTO has not established separate classification and separate status for each of the inventive Groups (See Remarks filed 15 March 2007, Page 2, Lines 28-29), applicants' attention is drawn to Office Action mailed 15 September 2006, Page 2, item 7, Lines 19, 21, 24 and 26, wherein Class/subclass for each inventive group is clearly mentioned. On page 4 at Lines 1-2 of said Office Action, further clarification is presented that classification is a combination of Class and subclass. Thus, contrary to applicants' assertion, USPTO has clearly established separate classification and status for each one of the inventive groups I-IV in the above-cited restriction requirement.

Applicants' argument regarding non-burdensome examination of Claims 1-17 in one single application and statement, "according to MPEP, when Claims can be examined together without undue burden, the USPTO must examine the claims on the merits even though these are directed to independent and distinctive inventions" is indicative that examining all the Claims 1-17 in one single application will be burdensome. Especially when the claims are drawn to "independent and distinct inventions". The Office Action mailed 15 September 2006 at page 3, Lines 20-30 clearly establishes that the search strategies for each of the 4 inventive groups requires different key words and the patentability criteria in each case is different. Also, the burden lies not only in the search of U.S. patents, burden also lies in the search for literature and foreign patents and examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness and scope of enablement. Clearly, different searches

and issues are involved with each inventive Group indicated in the Restriction requirement contained in the Office Action mailed 15 September 2006.

Applicants' arguments presented in the communication filed 15 March 2007 in response to Office Action mailed 15 September 2006 have been fully and carefully considered, however, those arguments are not persuasive because of the reasons of record on pages 2-4 in the Office Action cited *supra* and for the additional reasons discussed above. Therefore, the restriction requirement in the Office Action mailed 15 September 2006 is deemed proper and is made FINAL. Accordingly, Claims 1-5 and 10-17 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR §1.142(b) and MPEP §821.03.

5. Claims 6-9 are examined on merits.

Information Disclosure Statement

6. The Information Disclosure Statement (i.e., IDS) filed 19 November 2004 has been made of record, considered and duly initialed 3 sheets of Form USPTO/SB/08A are enclosed with this Office Action.

Priority

7. Claim for domestic priority under 35 U.S.C. §121 to non-Provisional U.S. Application Serial Number 10/2118,109 filed 14 August 2002, now U.S. Patent 6,743,425 is acknowledged.

Objection To Specification

8. The specification is objected to because Line one of first page of specification, in its present form does not properly recite the application priority data. The first line of the first page of the specification should indicate that the instant application claims priority to U.S. Non-provisional application and further indicate that said application is now a U.S. Patent.

Objection To Claims – Minor Informalities

9. Claims 6-9 objected to because of the following informalities:

Claim 6 is objected to because of the phrase "increasing the size of a growth plate in an abnormal bone". The connotation "an abnormal bone" is not befitting to the " increase in size of a bone growth plate" because the bone is sometimes abnormal for reasons other than the mere elongation or length of the bone. Furthermore, the length of bone may not make the bone abnormal, it may only be a property more prevalent in a given population. E.g., the height of an individual depends on the length of fibula and tibia or each of the vertebrae in the spinal column. An individual may not have an abnormal height, i.e., dwarf, yet the bone plate may still be elongated to make said person taller.

All other claims depend directly or indirectly from the objected claim 9 and are, therefore, also objected for the reasons set forth above.

Claim Rejections - 35 USC §102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

11. Claims 6-8 are rejected under 35 U.S.C. §102(b) as anticipated by Suda et al. (Proceedings of National Academy of Sciences of the United States of America, Volume 95, Pages 2337-2342, 1998).

Claims recite, "a method to increase the size of a bone growth plate in an abnormal bone through administering guanylyl cyclase B activator (GC-B-a), wherein said activator is a peptide and said peptide is a C-type natriuretic peptide (i.e., CNP).

Regarding Claims 6-8, Suda et al. teach a method to increase bone growth in mouse tibiae treated with CNP (Figure 3D). The CNP activates GC-B (Abstract, Lines 1-15). The increase in bone growth was demonstrated through measuring the total longitudinal bone length and proximal and distal cartilaginous primordia as well as osteogenuc center by a linear ocular scale before and after treatment, i.e., administration of CNP (Page 2138, Column 1, Lines 36-

40). Note that cartilaginous growth plate is located at both end of vertebrae and long bones Abstract, Lines 2-4). Tibiae are long bones. Thus, Suda et al. teach each and every element described in Claims 6-8.

Therefore, the reference is deemed to anticipate the cited claims.

12. Claims 6-9 are rejected under 35 U.S.C. §102(b) as anticipated by Suda et al. (Proceedings of National Academy of Sciences of the United States of America, Volume 95, Pages 2337-2342, 1998) with evidence provided by Suda et al ((Biochemical and Biophysical Research Communications, Volume 223, Pages 1-6, 1996) i.e., Suda et al'96).

Claims recite "a method to increase the size of a bone growth plate in an abnormal bone through administering guanylyl cyclase B activator (GC-B-a), wherein said activator is a peptide and said peptide is a C-type natriuretic peptide (i.e., CNP), wherein said CNP is a CNP-22.

Regarding Claims 6-9, Suda et al. teach a method to increase bone growth in mouse tibiae treated with CNP (Figure 3D). The CNP activates GC-B (Abstract, Lines 1-15). The increase in bone growth was demonstrated through measuring the total longitudinal bone length and proximal and distal cartilaginous primordia as well as osteogenuc center by a linear ocular scale before and after treatment, i.e., administration of CNP (Page 2138, Column 1, Lines 36-40). Thus, Suda et al. teach each and every element described in Claims 6-8. Please note that more than one CNP are known in the art, e.g., CNP-22 (See Suda et al'96 (Figures 4 and 5). Thus, Suda et al. teach each and every element described in Claims 6-9.

Therefore, the reference is deemed to anticipate the cited claims.

Note that in this rejection under 35 U.S.C. §102(b), Suda et al ((Biochemical and Biophysical Research Communications, Volume 223, Pages 1-6, 1996) i.e., Suda et al'96) is not applied as a prior art, rather Suda et al'96 merely supports Suda et alto establish that CNP-22 is an art known CNP.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § ***102***(f) or (g) prior art under 35 U.S.C.§ 103(a).

15. Claims 6-9 are rejected under 35 U.S.C. § 103(a) as obvious over the combined teachings from Suda et al. (Proceedings of National Academy of Sciences of the United States of America, Volume 95, Pages 2337-2342, 1998) in view of Suda et al ((Biochemical and Biophysical Research Communications, Volume 223, Pages 1-6, 1996) i.e., Suda et al'96).

Claims recite "a method to increase the size of a bone growth plate in an abnormal bone through administering guanylyl cyclase B activator (GC-B-a), wherein said activator is a peptide and said peptide is a C-type natriuretic peptide (i.e., CNP), wherein said CNP is a CNP-22.

Teaching from Suda et al. have already been discussed in item 12 *supra.* Suda et al., however, do not teach a CNP-22. Suda et al'96 teach that CNP-22 enhanced the growth of osteoblasts which is one of the means to increase bone central plate growth.

One having ordinary skill in the art at the time of the claimed invention would have been motivated to modify/combine the teachings from Suda et al'96 with those from Suda et al. because both Suda et al'96 and Suda et al. teach a method to increase bone growth, wherein CNP activates GC-B and Suda et al'96 teach that CNP to be CNP 22.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Suda al's teachings according to those from Suda et al'96 to obtain a method to increase the size of bone growth plate via administering a peptide, said peptide being CNP wherein said CNP is CNP-22.

From the teachings of the references cited *supra*, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

16. For reasons aforementioned, no Claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached at (571)-272-0925 Monday through Thursday 7:30 A.M. to 6:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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June 7, 2007

DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 128 1657